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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Regarding: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. THUMB-604DIV
MODULAR BASAL THUMB JOINT IMPLANT

Supplemental Appeal Brief for Appellant

Attention: On Appeal from Group Art Unit 3738
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I certify that this correspondence (51 sheets total) is deposited with the United States Postal Service in an envelope with sufficient postage as first class mail addressed to the Patent and Trademark Office address above on April 3, 2009:

Christopher John Rudy: Christopher John Rudy 4/3/2009.

Sir:

Thank you for the 02/10/2009 Office communication with its accompanying communication, which indicated that the Reply Brief filed on November 9, 2008 had been considered and entered, for the 03/02/2009 Office communication with its accompanying ORDER RETURNING UNDOCKETED APPEAL TO EXAMINER, and for the 03/10/2009 Office communication with its **Notification of Non-Compliant Appeal Brief (37 CFR 41.37)**. In reply to the lattermost Office communication, please consider this supplemental brief in support of the patentability of the claims on appeal. No fee is due for submission of the present supplemental brief.

The present brief incorporates material from the Brief for Appellant filed on February 8, 2008 and the Corrected Brief by Replacement Brief Section filed on June 12, 2008.

The present supplement brief includes all the required appendices, even though the Applicant had filed all the required appendices with his Brief for Appellant. This is shown by the 06/09/2008 Office communication with its **Notification of Non-Compliant Appeal Brief (37 CFR 41.37)** that only required a new summary of the invention section (box 4.a.) without more. If all the required appendices had not been filed, that Notification would have indicated it. It is also shown by a return receipt postcard, the pertinent side of which is reproduced on the next page. If thirty-four sheets of appendices, i.e., all required appendices, were not received, the Office would have indicated it by crossing out that line of the receipt pursuant to MPEP 503.

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Christopher John Rudy
PTO#31873
Feb 6, 2008 A.D.

The above is instructive. One can notice that the Board in the ORDER mentioned above found that the Evidence Appendix and Related Proceedings Appendix were, to quote, "missing." The Examiner, on the other hand, was quick to blame the Applicant for the missing appendices and, in light of the above, to blame quite wrongly, stating, "Applicant's representative failed to include ..." (emphasis supplied). Such an attitude on the part of the Examiner is displayed elsewhere in the record of the present application, reaching to the very rejections addressed here.

Real Party in Interest

The real party in interest is BioPro, Inc., Port Huron, MI.

Related Appeals and Interferences

Appeals in parent application No. 09/352,472, of which this is divisional, may have a bearing on this appeal. These are Nos. 2003-0155 dated March 13, 2003 and 2007-0570 dated June 14, 2007.

Status of Claims

Claims 1-20 have been canceled. Claims 21-42 are pending, with claims 38 and 39 allowed and claims 27, 30 and 33 allowable over the art of record. Claims 21-26, 28, 29, 31, 32, 34-37 and 40-42 stand rejected and are on the present appeal.

Status of Amendments

No amendment was filed subsequent to final rejection.

Summary of Claimed Subject Matter

With respect to independent claim 21, the invention resides in a modular basal thumb joint implant (title, page 3, lines 2-3 and 13-22, page 6, line 6, page 7, lines 4 and 8-11; FIGS. 1-13 including 4-9, Nos. 10, 20 and 100). It has a head of a size and having an articular surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock, with the head attachable to the stem (page 3, lines 16-22, page 7, lines 4 and 8-11, page 8, lines 1-4, 6-9, 12 and 14-15, page 9, lines 6 and 10-12, from page 9, line 20, to page 10, line 6; FIGS. 4-9 and 13, Nos. 9, 10, 15, 20, 25, 100). Claim 21 also requires that the head have a single, smooth, generally hemispherical, medio-proximally directed articulating surface (page 3, lines 3-4, 14 and 16-17, page 7, lines 1-2 and 12-16, page 10, lines 9 and 12-13; FIGS. 1, 4-9, 13, Nos. 10, 11 and 31) and a generally abrupt, distally directed, planar end to the head which defines an end to the articulating surface and has a center (page 3, lines 5 and 18, page 7, lines 15-18, page 9, line 16; FIGS. 1-4, 7, 9-13, Nos. 10 and 12) with the articulating surface continuous as to its spehericity and uninterrupted up to the end of the articulating surface (page 3, lines 3-4, 14 and 16-17, page 7, lines 12-13 and 15, page 10, lines 9 and 12-13; FIGS. 1-4 and 9-13, Nos. 10, 11 and 31). It also requires that the stem, when attached to the head, projects from the head along an axis, which arises from the generally planar end to the head (page 3, lines 6-7 and 14-16, page 8, lines 12 and 20-14; FIGS. 1, 4, 7, 9-10, 12-13, Nos. 12, 20 and 21) plus has feature(s) as follows:

A) a general angle of projection from the head that is acute in relation to the generally planar end to the head (page 3, lines 7-9 and 14-16, page 8, lines 20-21; FIGS. 1, 4, 7, 10, 12 and 13, Nos. 12, 20 and 21);

B) a flanged cross-sectional stem profile, which, when taken in cross-section perpendicularly to the stem, is in a tri-flange shape, with three flanges without notches extending distally on the stem (page 3, lines 10 and 14-16, from page 8, line 24 to page 9, line 3, page 9, lines 13-14, page 11, line 7, page 12, lines 6-7; FIGS. 1, 2, 4, 5, 7, 10, 12 and 13, Nos. 20, 21, 51, 58);

C) an inwardly curved stem (page 3, lines 11 and 14-16, page 4, lines 4-13, page 9, lines 14-15; FIGS. 1, 4, 7, 10, 12 and 13, Nos. 10 and 20; and/or

D) an eccentric head site for the stem, which is offset from the center of the generally planar end of the head (page 3, lines 12 and 14-16, page 4, lines 4-6, page 9, lines 15-16; FIGS. 1, 4, 12 and 13, Nos. 10 and 20).

With respect to independent claim 40, the invention also resides in a modular basal thumb joint implant (title, page 3, lines 2-3 and 13-22, page 6, line 6, page 7, lines 4 and 8-11; FIGS. 1-13 including 4-9, Nos. 10, 20 and 100). It includes a

head of a size and having an articular surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock, with the head attachable to the stem (page 3, lines 16-22, page 7, lines 4 and 8-11, page 8, lines 1-4, 6-9, 12 and 14-15, page 9, lines 6 and 10-12, from page 9, line 20, to page 10, line 1; FIGS. 4-9 and 13, Nos. 9, 10, 20, 100). It has head and stem modularity such that the head is removably attachable to the stem (page 3, lines 16-22, page 7, lines 4 and 8-11, page 8, lines 6-9, from page 9, line 20, to page 10, line 6; FIGS. 4-9 and 13, Nos. 9, 10, 15, 20, 25, 100).

Grounds of Rejection to Be Reviewed on Appeal

All issues for review fall under 35 USC 103(a) as follows:

1. Are not claims 21, 22, 25, 26, 28, 29, 40 and 41 patentable over McLaughlin, U.S. patent No. 5,507,818?
2. Is not claim 23 patentable over McLaughlin in view of Townley, U.S. patent No. 2,934,065?
3. Is not claim 24 patentable under over McLaughlin in view of Lane et al., U.S. patent No. 5,674,297?
4. Are not claims 31, 32 and 34-36 patentable over McLaughlin in view of Abouaf et al., U.S. patent No. 5,871,547?
5. Is not claim 37 patentable over McLaughlin in view of the Wright Medical Technology brochure of record for the Swanson Titanium Basal Thumb Implant?
6. Is not claim 42 patentable over McLaughlin in view of "ASTM, 1998," presumably ASTM F 1377-98?

Argument

In the record and in this brief, the Appellant traverses all adverse statements and all grounds of rejection concerning the present application. The Appellant contends the following in support of the patentability of the claims on appeal:

1. Claims 21, 22, 25, 26, 28, 29, 40 and 41 are patentable over McLaughlin.

McLaughlin discloses a multipolar joint endoprosthesis. In general, it consists of multiple wedge-shaped, cylindrical components rotating perpendicular to their planes of effacement, plus proximal and distal components. The proximal component is:

> "contoured to fit the the proximal side of a surgically prepared joint (i.e., the glenoid fossa of the gleno-humeral joint, the acetabulum of the hip, etc.)"

and the distal component is:

> "contoured to fit the distal side of the surgically prepared joint or into the surgically prepared

> intramedullary canal distal to the involved joint (i.e., intramedullary canal of the humerous, hip, etc.)."

See, column 1, lines 19-32. Problems in the art are noted at column 1, lines 5-10: dislocation, component dissociation, bony wear, acetabular protrusio, pain, polyethylene wear, limited range of motion, etc. At column 1, lines 48-56, it is stated:

> "Since there is no motion at the bone-prosthesis interfaces, it is hypothesized that many of the problems of previously proposed endoprostheses would be resolved (i.e., bony wear, acetabular protrusio, pain, etc.). In addition, the components are inseparable except by surgical manipulation, as noted above, avoiding the problems of dislocation, dissociation of components, etc. Finally, by allowing motion at multiple component interfaces, the problems of polyethylene/component wear and limited range of motion are eliminated."

Within the paragraph bridging columns 1 and 2, from column 1, line 66, to column 2, line 2, McLaughlin states:

> "[T]he present invention is represented as a hip endoprosthesis. However, it is not meant to imply that the present invention is limited to use in the hip."

In detail, as at column 2, lines 33-35, McLaughlin states:

> "The proximal component 12 is firmly affixed to the proximal bony landmark (e.g., pelvis) 14 by means of methylmethacrylate bone cement, screws 20, bony ingrowth, etc., in such a way that no motion occurs at the proximal component-bone interface 17."

See, FIGS. 1 and 3-5. Also, as set forth at column 2, lines 46-49, a screw tract 23 is provided in the proximal component 12.

Claim 21

McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

First, it relates to large ball and socket joints of the shoulder and hip. Manifestly, the problems addressed are those of total hip and shoulder joints. Nothing else is taught, expressly or impliedly, even by the general word, "etc." Thus, the cylindrical components 11 of McLaughlin are large and would not be transferable by size reduction to a small joint. Rather, such an arrangement with its plurality of cylindrical components 11, if it could be envisioned implanted in a small joint, would cause pain and tissue damage such as by stretching of ligaments and tendons. In contrast, claim 21 requires a modular basal thumb joint implant with a head of a size and having an articular

surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock. Compare, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph, which sets forth part of a declaration from Patrick E. Pringle, president of BioPro, Inc., regarding hip and shoulder art not analogous because of size, configuration and implant situs. Giving such evidence weight, akin to that given to that declaration by the Board in Appeal No. 2003-0155 for the finger art of Klawitter et al., U.S. patent No. 5,782,927, helps show how hip or shoulder art would not suggest a modular basal thumb joint implant. See, Related Proceedings Appendix, p. RPA 8, sole full paragraph. The Board in Appeal No. 2007-0570 held too that Smith et al., U.S. patent No. 3,314,420 for a prosthetic implant and methods of making the same, which depicts a femoral component for a hip implant and recites a long list of other implants and products in column 16, does not teach a basal thumb joint implant in the parent. See, Related Proceedings Appendix, p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. ___ [82 USPQ2d 1385, 1397] (2007); In re Oetiker, 977 F.2d 1443 [24 USPQ2d 1443, 1445-1446] (Fed. Cir. 1992).

Second, what the Examiner takes for a "head" in McLaughlin is the proximal component 12. That, properly understood, is not a head of a joint or joint prosthesis. The proximal component 12 is fixed with bone screws 20, glue, or bony ingrowth (generally through a rough or porous surface) so that its hemispherical surface does not articulate, in a socket or elsewhere. It has adjusting screw tract holes 23 and holes for the screws 20 penetrating its hemispherical surface to render it discontinuous. In contrast, claim 21, in addition to that noted above, requires a single, smooth, generally hemispherical, medio-proximally directed articulating surface, with the articulating surface continuous as to its spehericity and uninterrupted up to the end of the articulating surface. Such art is diametrically opposed, and McLaughlin would be inoperable for its intended purposes if his proximal component 12 were to move. Inoperable art cannot be employed to establish a case of obviousness. See, United States v. Adams, 383 U.S. 39 [148 USPQ 479, 483] (1966); In re Gordon, 733 F.2d 900 [221 USPQ 1125, 1127] (Fed. Cir. 1984). Thus, along this line of reasoning the Board in Appeal No. 2003-0155 held that discontinuities in a generally hemispherical surface do not suggest to the ordinary artisan a hemispherical surface that is continuous as to its sphericity. See, Related Proceedings Appendix, p. RPA-8 (finger joint of the Klawitter et al. patent inoperable for its intended purpose if cuts in articulating surface removed, not suggestive of basal thumb joint implant). If McLauglin could be applied, it clearly teaches away from the smooth articulating head of the present claim, which would be strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; In re Hedges, 783 F.2d 1038 [228 USPQ 685, 687] (Fed. Cir. 1986).

Third, the Examiner takes as a "stem" the distal component 13. Taking it thus, it is clear that it does not attach to the "head," i.e., proximal component 12, to project therefrom. The cylindrical components 11 intervene. In contrast, claim 21 requires that the stem be attachable to the head, and when attached it projects from the head. Such emphasizes that the art proposed by the Examiner is widely divergent from and not at all structurally analogous to the art of the present claim. It is so widely divergent it teaches to parts intervening between the head and stem, thus teaching away from the claimed invention. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Furthermore, if the distal component 13 were attached to the proximal component 12, it would be attached perpendicularly. This is not an acute angle of projection found in the claim, and a perpendicular attachment would not suggest an acute one.

Moreover, there nothing eccentric in the attachment of any component to the proximal component 12 of McLaughlin. The site of attachment to the proximal component 12 is directly centered. See, FIGS. 1 and 3-5. In contrast, the eccentric attachment site of the present claim is defined as being "offset from the center of the generally planar end of the head." A standard, central situs of attachment does not suggest an eccentric one.

Finally, it cannot be properly said that it would have been obvious to employ McLaughlin's disclosure for a relevant teaching in a modular basal thumb joint implant as the ordinary artisan would understand that the body is made of many joints and that when the thumb joint has been injured or diseased it would be desirable to replace it with a prosthesis. That statement of the Examiner is inaccurate and provides nothing to motivate the ordinary artisan to modify McLaughlin into the present claim.

Thus, independent claim 21 distinguishes over McLaughlin.

Claim 22

Claim 22 depends on claim 21. By virtue of its dependence on claim 21, claim 22 distinguishes over McLauglin.

Furthermore, claim 22 requires the general angle of projection that is acute in relation to the generally planar end to the head. As explained above for claim 21, the "stem" of McLaughlin would attach to the "head" perpendicularly to project therefrom. Note, McLaughlin, FIG. 3, features 12, 22 and 26, and 13, 21 and 25. Perpendicular attachment does not suggest acuity; it teaches away, which is strong evidence of unobviousness. Then too, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12, to project from it, it would destroy the operability and intents of McLaughlin. An inoperable reference cannot negative patentability, and the

intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 25

Claim 25 depends on claim 21. By virtue of its dependence on claim 21, claim 25 distinguishes over McLauglin.

Furthermore, claim 25 requires the eccentric head site for the stem. As explained above for claim 21, McLaughlin's site of attachment to the proximal component 12 is on center. See, FIGS. 1 and 3-5. In contrast, the eccentric attachment site of the present claim is defined through its dependence on claim 21 as being "offset from the center of the generally planar end of the head." A standard, central situs of attachment does not suggest an eccentric one; it teaches away from such a feature, which is strong evidence of unobviousness. Adams, 383 U.S. 39 [148 USPQ at 483-484]; Hedges, 783 F.2d 1038 [228 USPQ at 687]. Moreover, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12 to project therefrom, it would destroy the operability and intent of McLaughlin. An inoperable reference cannot negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127].

Claim 26

Claim 26 depends on claim 22. By virtue of its dependence on claim 22, thence 21, claim 26 distinguishes over McLauglin.

Furthermore, the Examiner admits that neither the flanged cross sectional stem profile nor the inwardly curved stem is rendered obvious by McLaughlin. As explained above with respect to claim 25, neither is the eccentric head site for the stem.

Claim 28

Claim 28 depends on claim 21, and further requires that the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in that cup. By virtue of its dependence on claim 21, claim 28 distinguishes over McLauglin.

As particularly explained above in the argument for claim 21, McLaughlin's fixed "head," i.e., proximal component 12, is not a head in a sense of having a smooth generally hemispherical articulating surface as required hereby; it teaches away from this invention. And, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12 to

project therefrom, it would destroy the intent and operability of McLaughlin. Teaching away is strong evidence of unobviousness; an inoperable reference cannot negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 29

Claim 29 depends on claim 22, and further requires that the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in that cup. By virtue of its dependence on claim 22, thence 21, claim 29 distinguishes over McLauglin.

As particularly explained above with respect to claim 25, the eccentric head site for the stem is not rendered obvious by McLaughlin. And as particularly explained above for claim 28, McLaughlin's fixed "head," is not a head in the sense of having a smooth generally hemispherical articulating surface; it teaches away. And if McLaughlin's "stem" were to attach to his "head" to project therefrom, it would destroy his intents and operability. Teaching away is strong evidence of unobviousness; an inoperable reference does not negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 40

Jepson claim 40 admits as prior art basal thumb joint implants with a head for mounting and articulating in prepared trapezium and a stem for intramedullary insertion in metacarpal bone. The improvement therewith is head and stem modularity such that the head is removably attachable to the stem.

As set forth within the arguments set forth with respect to claim 21 and applicable here to independent claim 40 as well, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

For one thing, McLaughlin relates to large ball and socket joints of the shoulder and hip. The problems addressed are those of total hip and shoulder joints, nothing else, even by the word, "etc." The cylindrical components 11 of McLaughlin are large and would not be transferable by size reduction to a small joint. Rather, such an arrangement with its plurality of cylindrical components 11, if it could be envisioned implanted in a small joint, would cause pain and tissue damage such as by stretching of ligaments and tendons. In contrast, claim 40 requires a modular basal thumb joint implant with a head of a size and

having an articular surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock. Compare, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph, Mr. Pringle's declaration, regarding hip and shoulder art not analogous because of size, configuration and implant situs. Giving such evidence weight, akin to that given to that declaration by the Board in Appeal No. 2003-0155, helps show how hip or shoulder art would not suggest a modular basal thumb joint implant. See, Related Proceedings Appendix, p. RPA 8, sole full paragraph. The Appeal No. 2007-0570 held that Smith et al., U.S. patent No. 3,314,420, which depicts a femoral implant component for a hip and recites a long list of other implants and products in column 16, does not teach a basal thumb joint implant. See, Related Proceedings Appendix, p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

For another thing, what the Examiner takes for a "head" in McLaughlin, i.e., the proximal component 12, properly understood is not a head of a joint or joint prosthesis. That component 12 is fixed with bone screws 20, glue, or bony ingrowth so that its hemispherical surface does not articulate. That is opposite this claim, and McLaughlin would be inoperable for the stated intended purposes if the component 12 were to move. Inoperable art cannot be employed to establish obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127].

Thus, independent claim 40 distinguishes over McLaughlin.

Claim 41

Claim 41 depends on claim 40. By virtue of its dependence on claim 40, claim 41 distinguishes over McLaughlin.

Furthermore, claim 41 requires an acute general angle of projection of the stem with respect to the non-articular surface of the head. The Examiner takes as a "stem" the distal component 13, which clearly does not attach to the "head," i.e., proximal component 12, to project therefrom. The cylindrical components 11 intervene. In contrast, claim 41 requires that the stem project from the head, and this without intervening components such as the cylindrical components 11. The art proposed by the Examiner is widely divergent from and not at all structurally analogous to the art of the present claim. It is so widely divergent it teaches to parts intervening between the head and stem, thus teaching away from the claimed invention. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Hedges, 783 F.2d 1038 [228 USPQ at 687]. In fact, if the distal component 13 were to be attached to the proximal component 12 in the manner of the present claim, eliminating the cylindrical components 11, it would render McLaughlin inoperable.

Inoperable art cannot be applied. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127].

Also, should McLaughlin's distal component 13 be attached to the proximal component 12, it would be attached perpendicularly. This is not an acute angle of projection required by this claim, and a perpendicular attachment would not suggest an acute one.

2. Claim 23 is patentable over McLaughlin in view of Townley.

Claim 23 depends on claim 21. It further requires the flanged cross-sectional stem profile.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious. Townley, if both McLaughlin and Townley could be applied, adds nothing that would render base claim 21 obvious, even with respect to its stem limitation "B." As set forth above with respect to base claim 21, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Townley as well, representing a femoral component for a hip implant, is not applicable to a basal thumb joint implant. This, again, has been verified by Mr. Pringle, and confirmed by the Board previously. See, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph; Related Proceedings Appendix, p. RPA 8, sole full paragraph, and p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. See also, In re Sernaker, 702 F.2d 989 [217 USPQ 1, 5] (Fed. Cir. 1983) (references to be related to one another).

Among other things, too, Townley lacks modularity, size of the claimed head and stem, a generally planar end to his head, and so forth. If the features of Townley were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example, some possibilities: should there be a fixed distal component? an articulating distal component as head? a generally planar end to a fixed distal component? a generally planar end to an articulating head? a cupped fixed distal component? a cupped articulating head? a simple stem? intervening moving components? a tri-flanged stem? modularity? no modularity? if the size of the implant were made small, should not a tri-flange stem be jettisoned, say, as taught by the Swanson Titanium Basal Thumb Implant (Wright)? should, if made small, modularity be jettisoned as taught by Wright? Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148

USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001).

3. Claim 24 is patentable under over McLaughlin in view of Lane et al.

Claim 24 depends on claim 21. It further requires the inwardly curved stem.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious. Lane et al., if it could be applied with McLaughlin, adds nothing that would render base claim 21 obvious, even with respect to its stem limitation "C."

As set forth above with respect to base claim 21, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

Lane et al. represents finger joint art, which is not related to basal thumb joint art. The Examiner admitted in the parent case (05/25/01 Office action, page 2) that finger joint art is independent and patentably distinct from, and unrelated to, basal thumb joint art. He cited different classifications, 623/21.15 vs. 623/21.11, and stated:

> "In the instant case, the different inventions are two types of joints which operate differently and are structurally different. The finger or digit joint is considered an anarthrodial joint, whereas the thumb is a'saddle joint.'"

Moreover, the finger joint of Lane et al. has multiple articulation surfaces and is a total joint implant, and it does not have head and stem modularity. Thus, in the first instances it does not have a single articulating surface that is continuous as required through the base claim 21. Accordingly, it resembles the implant of Klawitter et al., U.S. patent No. 5,782,927. The Board in Appeal No. 2003-0155 stated about such art:

> "[W]e fail to perceive any teaching, suggestion or incentive which would have led one of ordinary skill in the art to manufacture the Klawitter joint implant without the cuts ... for to do so would render the device unsuitable for its intended purpose. Continuing on the same theme, there is no evidence from which to conclude that one of ordinary skill in the art would have found it obvious to utilize the Klawitter joint implant on the thumb, in view of the different considerations needed for a thumb joint, which are attested to on page 10 of the Pringle declaration."

See, Related Proceedings Appendix, p. RPA-8; Evidence Appendix, p. EA-5, second full paragraph, through p. EA-6. Moreover, the Examiner admitted in the same 05/25/01 Office action, page 2, last paragraph, that modular basal thumb joint art was patentably

distinct from the non-modular art. Non-modular finger joint art is even more unrelated. Only analogous art can be applied. See, KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

If the features of Lane et al. were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example, some possibilities: should there be a fixed distal component? an articulating distal component as head? a generally hemispherical articulating head? a complex head including shoulders and sphere? a straight stem? a curved stem? intervening moving components? modularity? no modularity? if the size of the implant were made small, should not a curved stem be jettisoned, say, as taught by Wright? should, if made small, modularity be jettisoned as taught by Lane et al., and Wright? At best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

4. Claims 31, 32 and 34-36 are patentable over McLaughlin in view of Abouaf et al.

Claims 31 and 32 depend on claims 28 or 29, and further require tapered walls to the cup and trunion to secure the head and stem together. Claims 34, 35 and 36 depend on claims 21, 22 or 28, and further require a ceramic head and a metal stem.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Abouaf et al., if both McLaughlin and it could be applied, adds nothing that would render base claim 21 obvious.

Abouaf et al., comparable to Townley discussed with respect to claim 23, in one aspect concerns a hip implant, here total, which is not applicable to a basal thumb joint implant. This, again, has been verified by Mr. Pringle, and confirmed by the Board previously. See, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph; Related Proceedings Appendix, p. RPA 8, sole full paragraph, and p. RPA-20, second full paragraph. In another aspect, Abouaf et al. represents a simple, non-modular total knee joint implant. See, FIG. 4. That ginglymous joint implant is not related to a basal thumb joint implant, much less the pertinent art of a modular basal thumb joint implant. Only pertinent art can be applied. See, e.g.,

KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Sernaker, 702 F.2d 989 [217 USPQ at 5] Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

Among other things, too, Abouaf et al. lacks size of the claimed head and stem, a generally hemispherical articulating head, a generally planar end to his head, and so forth. If the features of Abouaf et al. were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example: should there be a fixed distal component? an articulating distal component as head? a generally planar end to a fixed distal component? a generally planar end to an articulating head? a generally spherical head? a knee with its condyles? a simple stem? intervening moving components? if the size of the implant were made small, should not modularity be jettisoned, say, as taught by Wright? Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001).

Claim 31

The proposed combination fails to suggest tapered walls for securing a head to a stem in a modular basal thumb joint implant as claimed through claims 28 and 21. In particular with the above matter applicable generally, if combined, would the combination lead the ordinary artisan to modularity or not? If so, would the combination lead to the straight, cylindrical walls of McLaughlin, or the tapered walls of Abouaf et al.? Where is there a suggestion to reduce the size of a hip, shoulder or knee implant? Many features of the combination teach away, which is strong evidence of unobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 32

The proposed combination fails to suggest tapered walls for securing a head to a stem in a modular basal thumb joint implant as claimed through claims 29, 22 and 21. In particular with the above matter applicable generally, if combined, would the combination lead the ordinary artisan to modularity or not? If so, would the combination lead to the straight, cylindrical walls of McLaughlin, or the tapered walls of Abouaf et al.? Where is there a suggestion to reduce the size of a hip, shoulder or knee implant? Many features of the combination teach away, which is strong evidence of unobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

Of note, too, is the acute general angle of projection required with the remaining elements through claim 22. Abouaf et al. teaches a standard perpendicular angle of projection for a hip (FIGS. 1-3) or no stem and head whatsoever (FIG. 4). McLaughlin, as explained with respect to claim 22, further would be inoperable with a stem to head attachment, ignoring that otherwise teaching a perpendicular angle of attachment. This is further evidence of inapplicability of the art and patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claims 34, 35 and 36, Taken Separately

A ceramic head with metal stem in a modular basal thumb joint is not suggested by the proposed combination, particularly in light of the subject matter additionally required not only by the base claim 21 on which claim 34 directly depends, but also claim 22 upon which claim 35 directly depends and requires acuity in attachment of the stem to the head, and claim 28 upon which claim 36 depends and requires a stem trunion and a cup in the head for receiving it. In addition to the arguments presented above, which are applicable hereto, note that if combined the combination would be vague about materials in general, and absent impermissible hindsight, gives not even general guidance as to what would be desirable for materials in a small modular basal thumb joint implant, which heretofore did not exist. The one-piece thumb joint of Wright was made entirely of metal, thus teaching away from ceramic in the small joint and teaching away from not only modularity but also a combination of a ceramic head and a metal stem in such an implant. This is additional strong evidence of patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

5. Claim 37 is patentable over McLaughlin in view of the Wright Medical Technology brochure (Wright).

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Wright, if both McLaughlin and it could be applied, adds nothing that would render base claim 21 obvious. Accordingly, by virtue of its dependence on claim 21, claim 37 distinguishes over the proposed combination.

Moreover, Wright is not applicable by itself or with McLaughlin. The Wright implant is a one-piece basal thumb joint implant. The present claimed invention is a modular basal thumb joint implant. The Examiner has fully admitted at least two times of record that one-piece basal thumb joint implants and modular basal thumb joint implants are independent and patentably distinct species. See, the 05/25/01 Office action in the parent application, pages 2-3, from whence came the present divisional

application; and, in the present application, the 10/12/2006 Office action, page 2, and the 01/17/2007 Office action, page 2. Thus, Wright is not related to the art of the present claims, and the Examiner has admitted it. McLaughlin, again which represents hip or shoulder implant art, as explained above with respect to claim 21, is not relevant art and not applicable. Nor is the basal thumb joint implant of Wright related to the shoulder or hip of McLaughlin. Only references related to the art of the claimed invention and related to other references in combination can be applied. See, Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. Moreover, even if these two disparate references could be applied to the present claims, they would not suggest the invention claimed. Among other things, Wright lacks a disclosure of modularity, a curved stem, a tri-flanged stem, an eccentric stem-to-head attachment site. Wright lacks disclosure of acute stem-to-head attachment; its attachment is perpendicular. Among other things, McLaughlin lacks disclosure of a head with a generally hemispherical articulating surface, size of the present claimed head and stem, generally acute site of attachment, tri-flanged stem, eccentric attachment, an inwardly curved stem, and so forth. If the features of these two references were combined, a person of ordinary skill would be left in the dark as to which features should be present: should there be a large head? a small stem? a square stem? if the size of the implant were made small, should not a tri-flange or curved stem be jettisoned in favor of a stout, square, straight stem, as found in Wright, which has the small implant? Clearly, too, if combined, there would be no modularity, or, if it were deemed that McLaughlin shows stem-and-head modularity as in a large hip joint implant, if a device were made small, modularity of stem-to-head should be jettisoned as taught by Wright; there would be a perpendicular stem-to-head attachment, not acuteness as claimed hereby; there would be stem-to-head attachment at the center of the rear of the head, not in the eccentric manner claimed hereby. Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance, but even general guidance is not enough to establish a case of obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531]. What is more, Dr. Leslie, a renowned hand surgeon, verified that he thought the one-piece basal thumb joint implant of Dr. Townley was a significant improvement over the implant of Wright; thus, if Wright were somehow considered relevant, its value is rebutted by that. See, Evidence Appendix, p. EA-8, first and third large paragraphs, p. EA-9, first paragraph.

6. Claim 42 is patentable over McLaughlin in view of ASTM F 1377-98.

Claim 42 depends on claim 40 and further requires a porous coating for bone interface.

As explained above with respect to claim 40, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. The ASTM, if both McLaughlin and it could be applied, adds nothing that would render base claim 40 obvious. Accordingly, by virtue of its dependence on claim 40, claim 42 distinguishes over the proposed combination.

Moreover, combining these references would lead plainly to a device that could not operate in articulation with the concavely prepared surface of trapezium bone stock. Note that McLaughlin's proximal component 12 can be fixed with bony ingrowth. This is what is provided by the ASTM. However, that bony ingrowth would be found on the generally hemispherical surface of the proximal component 12, thus rendering it impossible to articulate. And so not only would the combination make for inoperable articulation but it teaches away from articulation with a generally hemispherical surface. This is strong evidence of patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Conclusion

Reversal of the rejections is in order, and is requested.

Respectfully,

Dated: April 3, 2009 A.D.

Christopher John Rudy
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209 Huron Avenue, Suite 8
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Attmt: Claims Appendix (pp. CA-1 to CA-3)
Evidence Appendix (pp. EA-1 to EA-9)
Related Proceedings Appendix (pp. RPA-1 to RPA-22)

CLAIMS ON APPEAL

21. A modular basal thumb joint implant comprising the following parts:

a head including a single, smooth, generally hemispherical, medio-proximally directed, articulating surface, and a generally abrupt, distally directed, planar end to the head which defines an end to said articulating surface and has a center, said articulating surface being continuous as to its sphericity and uninterrupted up to the end of said articulating surface so that said articulating surface defines a truncated ball of a shape that is from substantially hemispherical to greater than substantially hemispherical; and

a stem, which is attachable to the head, and which, when attached to the head, projects from the head along an axis, which arises from the generally planar end to the head and includes at least one of the following features:

A) a general angle of projection from the head that is acute in relation to the generally planar end to the head;

B) a flanged cross-sectional stem profile, which, when taken in cross-section perpendicularly to the stem, is in a tri-flange shape, with three flanges without notches extending distally on the stem;

C) an inwardly curved stem;

D) an eccentric head site for the stem, which is offset from the center of the generally planar end of the head;

wherein said implant has its head of a size for mounting in and articulating with a correspondingly concavely prepared surface of

trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock.

22. The implant of claim 21, which has at least the general angle of projection from the head which is acute in relation to the generally planar end to the head.

23. The implant of claim 21, which has at least the flanged cross-sectional stem profile.

24. The implant of claim 21, which has at least the inwardly curved stem.

25. The implant of claim 21, which has at least the eccentric head site for the stem.

26. The implant of claim 22, which further includes at least one of the flanged cross-sectional stem profile, the inwardly curved stem, and the eccentric head site for the stem.

28. The implant of claim 21, wherein the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in said cup.

29. The implant of claim 22, wherein the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in said cup.

31. The implant of claim 28, which has tapered walls to said cup and said trunion for securing the head and stem together.

32. The implant of claim 29, which has tapered walls to said cup and said trunion for securing the head and stem together.

34. The implant of claim 21, wherein the head is made of a

suitable ceramic material, and the stem of a suitable metal.

35. The implant of claim 22, wherein the head is made of a suitable ceramic material, and the stem of a suitable metal.

36. The implant of claim 28, wherein the head is made of a suitable ceramic material, and the stem of a suitable metal.

37. The implant of claim 21, wherein the head has a 13-mm to 19-mm diameter.

40. In a basal thumb joint implant, which includes a head of a size and having an articular surface for mounting and articulating in association with a correspondingly concaveiy prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock, the improvement which comprises head and stem modularity such that the head is removably attachable to the stem.

41. The improvement of claim 40, wherein the head has a non-articular surface opposing the articular surface, and the head is attachable to the stem with a general angle of projection of the stem from the head that is acute in relation to the non-articular surface of the head.

42. The improvement of claim 40, which includes for bone interface a porous coating.

Declaration with Exhibits (37 CFR 1.132)

Submitted under a certificate of facsimile transmission accompanying an Amendment on April 17, 2007

Filed on April 17, 2007 (as shown by Auto-Reply copy below)

Entered by Examiner by 08/02/2007 Office action, Office Action Summary box 1 and page 2

USPTO 4/17/2007 6:40:17 PM PAGE 1/001 Fax Server

TO:Auto-reply fax to 810 982 5336 COMPANY:

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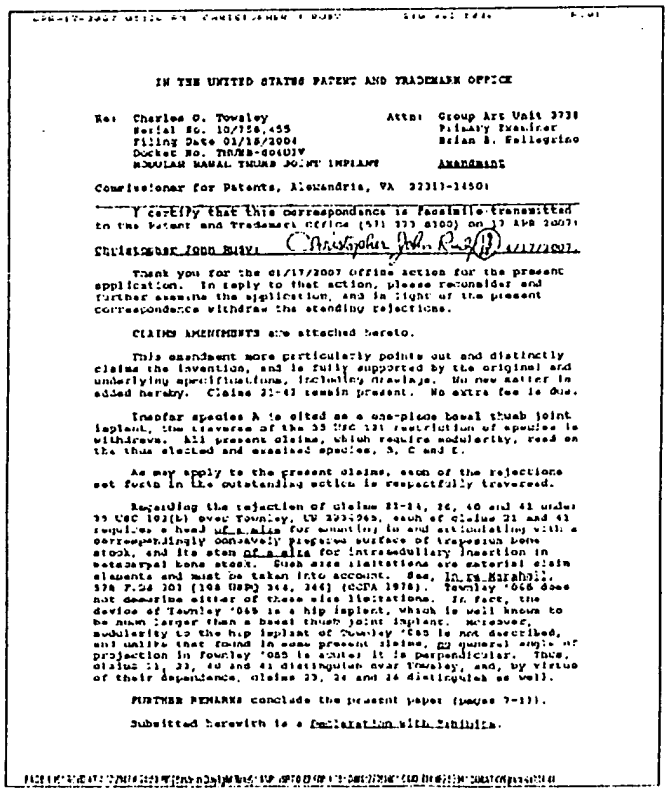
Received Cover Page ========>



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. TRMED-004DIV
MODULAR MANUAL THUMB JOINT IMPLANT

Attn: Group Art Unit 3738
Primary Examiner
Brian E. Pellegrino

Amendment

Commissioner for Patents, Alexandria, VA 22313-1450

I certify that this correspondence is facsimile transmitted to the Patent and Trademark Office (571) 273 8300) on 17 Apr 2007:

Christopher John Rogers 17/17/2007

Thank you for the 01/17/2007 Office action for the present application. In reply to that action, please reconsider and further examine the application, and in light of the present correspondence withdraw the standing rejections.

CLAIMS AMENDMENTS are attached hereto.

This amendment more particularly points out and distinctly claims the invention, and is fully supported by the original and underlying specifications, including drawings. No new matter is added hereby. Claims 21-41 remain present. No extra fee is due.

Insofar species A is cited as a one-piece basal thumb joint implant, the traverse of the 35 USC 121 restriction of species is withdrawn. All present claims, which require modularity, read on the thus elected and examined species, B, C and E.

As may apply to the present claims, each of the rejections set forth in the outstanding action is respectfully traversed.

Regarding the rejection of claims 21-24, 26, 40 and 41 under 35 USC 102(b) over Townley, US 3993065, each of claims 21 and 41 requires a head of a size for mounting to and articulating with a correspondingly concavely progress surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock. Such size limitations are material claim elements and must be taken into account. See, In re Marshall, 578 F.2d 301 (198 USPQ 344, 346) (CCPA 1978). Townley '065 does not determine either of these size limitations. In fact, the device of Townley '065 is a hip implant, which is well known to be much larger than a basal thumb joint implant. Moreover, modularity to the hip implant of Townley '065 is not described, and unlike that found in some present claims, no general angle of projection in Townley '065 is center it is perpendicular. Thus, claims 21, 22, 40 and 41 distinguish over Townley, and, by virtue of their dependence, claims 23, 24 and 26 distinguish as well).

FURTHER REMARKS conclude the present paper (pages 7-13).

Submitted herewith is a declaration with exhibits.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
Serial No. 10/758,455
Filing Date 01/15/2004
Docket No. THUMB-604DIV
For **MODULAR BASAL THUMB JOINT IMPLANT**

Declaration with Exhibits (37 CFR 1.132)

Attention: Group Art Unit 3738
Primary Examiner Brian E. Pellegrino

Commissioner for Patents, Alexandria, VA 22313-1450:

I, Christopher John Rudy, state and declare as follows:

I am the attorney of record (Reg. No. 31,873) in the present application and in parent Serial No. 09/352,472. I was attorney of record in the application that led to U.S. Pat. No. 6,096,084.

The inventive entity of the Townley '084 patent is the same as in the present application, Charles O. Townley. Both the invention of Townley '084 and the present invention were subject to assignment and have been assigned to the same owner, BioPro, Inc., with their assignments recorded in the Office on Reel 10155 Frames 892-894 and Reel 10116 Frames 869-870, respectively.

Attached hereto as Exhibits are copies of parts of declarations of record in the parent application, as follows:

Pages 1 (with postcard receipt) and 9-11 of the DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS of Patrick E. Pringle, filed on March 19, 2001.

Pages 1 (with postcard receipt), 3 and 4 of the DECLARATION OF MARK S. LESLIE, M.D., filed on May 22, 2000.

These verify among other things that hip implant art is not relevant to the art of basal thumb joint implants, and that the one-piece basal thumb joint implant of Dr. Townley was considered by Dr. Leslie to be clearly different from the Swanson titanium basal thumb joint of the Wright Medical Technology brochure, and that such is favorable for Dr. Townley's basal thumb implant.

All statements made herein of my own knowledge are true and on information and belief are believed to be true. Also, these statements were made with the knowledge that willful statements and the like so made are punishable by fine and/or imprisonment per 18 USC 1001 and such willful false statements may jeopardize the validity of this application or any patent issuing hereon.

Dated: April 17, 2007 A.D.

Christopher John Rudy

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Regarding: Charles O. Townley
Patent Application No. 09/352,472
Original Filing Date 07/14/99
CPA Filing Date Aug. 17, 2000
For BASAL THUMB JOINT IMPLANT

Attention: Group Art Unit 3738
Examiner Brian E. Pellegrino
Primary Examiner Bruce E. Snow

Commissioner of Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR 1.132 TRAVERSING REJECTIONS

I, Patrick E. Pringle, being warned that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent resulting hereon, state and declare as follows:

I am the undersigned, and am a citizen of the United States of America, and a resident of Smiths Creek, Michigan.

I am employed at BioPro, Inc., the assignor of the entire right, title and interest in the invention of the application of reference, being the current president of the corporation. I have worked at BioPro, Inc. for twelve years. Among my duties there, I assist in designing, evaluating and/or manufacturing prosthetic implants such as for the knee, elbow, hip, shoulder, big toe, and basal thumb joints. I am one of the co-inventors of U.S. patent No. 5,766,257 for an artificial joint having natural load transfer.

I understand that under 35 USC 103(a) claims of the present patent application stand rejected as being unpatentable over the applied references (which references I have reviewed, with copies thereof attached) as follows: 1) claims 1-8 over Kummer et al., U.S. patent No. 5,910,171; 2) claims 1-10, 12-14 and 16 over the "Townley Modular Shoulder" (BioPro brochure); 3) claims 17-20 over the BioPro brochure in view of the "Swanson Titanium Basal Thumb Implant" (Wright Medical Technology brochure); 4) claims 11 and 15 over the BioPro brochure in view of Bekki et al., U.S. patent No. 5,007,932. I believe that I have a sufficient understanding of the present invention, and formal drawings from the application, which pictorially illustrate principles and preferred embodiments of the invention, follow:

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Townley, 09/352472 Pringle DECLARATION, p. 9

I would respectfully disagree with the reasoning of the Examiner, and think that shoulder or hip joint art, and finger joint art, are not particularly related to basal thumb joint art.

Taking the shoulder joint as exemplary of what I understand that the Examiner considers to be more relevant from among the enarthrodial type joints of shoulder and hip, it first should be mentioned that I was shocked, saying, "No way!" when I heard that shoulder joint art, particularly a humeral implant, was being applied to a basal thumb joint. These joints are not related sufficiently to be interchangeable. (A hip, although not itself particularly relevant to basal thumb joint implant art either, perhaps would be more analogous.) Several considerations come to mind in support of this: size, configuration, and implant situs.

The size of a shoulder implant is vastly greater than that of a basal thumb implant. I fail to see how a person of ordinary skill in the art is given directions from the applied art to reduce the size of a large implant, intended for one part of the anatomy, a large part at that, to a smaller implant, intended for a different, small, remote part of the anatomy.

The configuration or shape of a humeral implant differs, and in some ways significantly, from a basal thumb joint implant as well. In general, for instance, humeral shoulder implants have more acute angles of attachments of their heads than do basal thumb joint implants. For example, the head to stem angle of the Townley Modular Shoulder is about fifty degrees whereas that of the Swanson Basal Thumb Joint appears to be nearly perpendicular. The angle of attachment of the basal thumb joint of the present invention preferably is about from sixty-five to seventy-five degrees, say, about seventy degrees. As well, typically, the heads of humeral shoulder implants span less than a hemisphere whereas those of basal thumb joints span more a hemisphere. The stems of humeral shoulder implants are, in general, relatively massive and not fluted to any pronounced degree. In contrast, the basal thumb joint implant stems are more slight, in general, and the basal thumb joint implant stem of the present invention preferably has a tri-flanged stem, for example, being T-shaped in cross-section. Moreover, a humeral shoulder implant often has a relatively large, solitary fin on the lateral side of the stem by the head for stabilization whereas no such solitary fin is found in basal thumb joint implants.

The situs of the implant differs significantly between the shoulder and the basal thumb. The humeral component of a shoulder implant has a stem designed for insertion into the upper reaches of a resected humerus, and has a head designed for mating with a glenoid socket cup or the glenoid socket itself. These parts of the anatomy differ significantly from the situs of the thumb. The shoulder is the most mobile joint in the body and is naturally an enarthrodial (ball and socket) type joint. The basal thumb, however, does not have naturally the mobility of the

shoulder, and, in nature, is not a ball and socket type joint but rather is a saddle joint. It is only in artificial prosthetic implantation that the basal thumb joint is converted, as it were, to a ball and socket type connection. The long bone of the upper humerus is shaped differently, both internally and externally, from that of the metacarpus, into which the differing stems go.

Furthermore, I question why it is that a person of ordinary skill has not reduced the size of either a hip or a shoulder implant to develop a good basal thumb implant. And as I see it, for example, with respect to the Swanson Basal Thumb Implant, a person of ordinary skill did not "look to other prior art prostheses for designing the structure of the implant."

With respect to a finger digit implant such as that of Bekki et al., my initial impression when I was informed that finger digit joint art was being applied to a basal thumb joint was that of being confounded. These joints are not related sufficiently to be interchangeable. Several considerations come to mind in support of this: configuration, materials and implant situs.

The configuration of a finger digit joint implant differs fundamentally from that of a basal thumb joint implant. First, a typical finger digit joint implant as represented by Bekki et al. has a discontinuous head with respect to sphericity whereas the basal thumb joint under consideration has a head with an articulating surface that is uninterrupted as to its sphericity. This is so that the peculiarities of the finger joint such as a lesser degree of mobility or tendon interference are taken into account. The stem, too, of the Bekki et al. implant does not resemble that of the basal thumb joint implant of the present invention, in particular in its preferred embodiments, which can be readily seen.

The materials of the Bekki et al. joint, even as a composite structure, do not resemble those of the present basal thumb joint having a modular ceramic head. The Bekki et al. joint is said to be preferably either of ceramic or can have a metal-based, ceramic-coated head, with the implant component itself still of one piece. In contrast, the modular basal thumb joint implant of the present invention which has a ceramic head is a two-part component, and prefers a monolithic ceramic head part attachable to a monolithic metal stem part. Moreover, quick bone ingrowth is not relevant to the head of the modular ceramic-headed basal thumb joint implant of the invention. Such a consideration would be counterproductive to functionality of the thumb joint and harmful to the patient.

As to the implant situs, as alluded to above, a finger digit joint is significantly different from a basal thumb joint, both in natural and in artificial implant environments. The finger joint, for one thing, is significantly constrained whereas the basal thumb joint has far more degrees of freedom of movement,

which is essential for a properly functioning joint.

It appears, therefore, that the application of the references noted above to the claims of the present invention is untenable.

All statements made herein of my own knowledge are true. All statements made herein on information and belief are believed to be true.

Dated: March 9, 2001

Patrick E. Pringle

Attachments

Townley, 10/758455 Decl. w/Exhibits (Exhibits)

Recd:
Amendment with Formal Drawings (7pp.) 5/16/00
(+3 sheets drwgs.)
Record of Interview 5/16/00
DECLARATION OF MARK S. LESLIE, M.D. 5/16/00
#39 pp (Cl. # 896)
Re: Townley
09/352,472
BASAL THUMB JOINT IMPLANT
Christopher John Rudy
PTO #31573 5/16/2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of

Charles O. Townley
Serial No. 09/352,472
Filing Date 07/14/99
For BASAL THUMB JOINT IMPLANT

To the attention of

Group Art Unit 3738
Examiner Brian E. Pellegrino

Commissioner of Patents
Washington, D.C. 20231

DECLARATION OF MARK S. LESLIE, M.D.

I, Mark S. Leslie, hereby state and declare that:

I am a citizen of the United States of America and resident of Traverse City, Michigan. Further, I am a licensed physician and orthopaedic surgeon practicing in Traverse City. I graduated with the M.D. degree in 1980 A.D., and have been certified by the American Board of Orthopaedic Surgeons since 1988. I specialize in surgery to the hand. Attached hereto is my Curriculum Vitae.

I understand that the claims of the present application have been rejected under Section 102(b), Title 35, United States Code, allegedly for a public use or sale of the invention prior to July 14, 1998. The Examiner stated in setting forth his rejection:

> Claims 1-20 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. In May of 1998, Charles O. Townley sold the implant to Dr. Leslie. A product can be sold if its confidentiality is agreed/-implied upon. However, no such agreement for the confidentiality of the implant was agreed upon in the statement/explanation of the sale. The purchaser, Dr. Leslie, of the product/invention which was sold by the inventor/-company was asked, "Let me know how this works." However, BIOPRO/Dr. Townley did not receive any feedback from the buyer, so it was assumed that the thumb implant worked fine. Further purchases by the original buyer, Dr. Leslie, reinforced the fact that it was working well. This is not experimental use of the invention, since no agreement to keep it confidential was stated and no reports were required. Proper experimentation requires positive and/or negative feedback.

I also understand that prior to the rejection, Dr. Townley's attorney, Christopher John Rudy, had reported to the Examiner the following information, as he understood it, pertinent thereto:

I wish to note the following:

Although Mr. Rudy's report to the Patent Office as set forth on the previous page would seem to be accurate and reasonable in general, in correction of some of Mr. Rudy's understandings of the invention as would pertain to me as reported on the previous page, as I recall, with respect to his stating that the head was too large, only the head at the large end of the spectrum appeared to be a bit too large; the head at the small end of the spectrum seemed to be a bit too small. However, the intermediate sizes of the heads did not seem to present significant problems in my estimation. Also, as I recall now, I thought that the tri-flanges and curved stem and so forth could be acceptable, but, being part of a new and different thumb joint implant, should necessitate a trial. In addition, I did not purchase the basal thumb joints of the present invention which I implanted; these were actually purchased by Munson Medical Center Hospital, at which I have staff privileges.

Attached hereto are FIGS. 1-13 of the invention from the present application of Dr. Townley. I received, on a first user basis from BioPro, Inc., non-modular thumb joint implants such as depicted in FIGS. 1-3 and 12. The stems had cross-sections like those depicted in FIGS. 5 and 6. FIG. 12 most accurately depicts how the thumb joint implants I received looked, and FIG. 13 shows in general how the implant looks when implanted. I understand that the basal thumb joint implants which I received were made of a cobalt alloy. I did not receive any modular joint implants such as depicted in FIGS. 4 and 7-9, nor do I recall any porous coating on the implants I received such as depicted in FIGS. 10 and 11.

I did consider my use of the basal thumb joint implants experimental, especially for the first year, since they were clearly different from the otherwise broadly analogous Swanson titanium basal thumb joint known then, and thus, again, their configuration should require a clinical trial to determine if the new basal thumb joint implants could be adequately employed in general. Before the critical date of July 14, 1998, I received and implanted in a patient one non-modular basal thumb joint of the present invention as referenced above.

Although no formal written agreement of confidentiality was entered into between me and BioPro, Inc., I understood that the basal thumb joint implant invention, which was paid for by Munson Medical Center, was to be tried in confidence, and any such disclosure of the invention was on a need to know basis. Thus, I informed my patients in whom the joints were to be implanted that I would be implanting an experimental joint, and, of course, so as to attain informed consent, these patients viewed the joint. However, I made no public disclosure of the invention, nor did I promote it among my colleagues. Thus, the invention was kept in appropriate confidence, especially during the critical period.

Also, although I understand that, based on the foregoing report from Mr. Rudy, he did not report to the Patent Office nor do I recall being expressly asked, "Let me know how this works," in contrast to that which the patent Examiner stated in setting forth his rejection, I understood that I was to keep track of results, but that reporting of results could be anecdotal. Thus, my reporting of results could be, and was done, informally. In general, I found that the joint performed fairly well, and I conveyed this at least on an informal basis to BioPro, Inc.

Accordingly, as I understand it, there was no public use by me nor non-experimentally-based sale of the present thumb joint invention before the critical date under 35 U.S.C. 102(b).

All statements made herein of my own knowledge are true, and all statements made herein on information and belief are believed to be true. Furthermore, these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under 18 USC 1001, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Mark S. Leslie

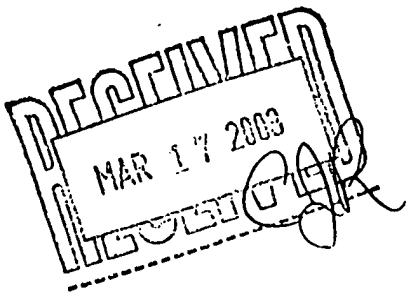
Date 5/10/00

Attmts: Attmt A (C.V.)
Attmt B (FIGS. 1-13)

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Ex parte CHARLES O. TOWNLEY

Appeal No. 2003-0155
Application No. 09/352,472

MAILED

MAR 13 2003

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before ABRAMS, FRANKFORT, and McQUADE, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-7, 21, 22, 24 and 25. Claims 18-20 have been allowed, claims 12-17 canceled, and claims 8-11, 23 and 26 withdrawn from consideration as being directed to a non-elected invention.

We AFFIRM-IN-PART.

BACKGROUND

The appellant's invention relates to a basal thumb joint implant. An understanding of the invention can be derived from a reading of exemplary claim 1, which has been reproduced below.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Whipple et al. (Whipple)	5,702,469	Dec. 30, 1997
Klawitter et al. (Klawitter)	5,782,927	Jul. 21, 1998

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Whipple.

Claims 1-7, 21, 22, 24 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Klawitter.

Claims 21 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Whipple.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the Answer (Paper No. 30) and the final rejection (Paper No. 25) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 29) and Reply Brief (Paper No. 32) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

Claim 1

> A basal thumb joint implant comprising a head including a single, smooth, generally hemispherical, medio-proximally directed, articulating surface, and a generally abrupt, distally directed truncation thereto, said generally hemispherical articulating surface being continuous as to its sphericity and uninterrupted up to said truncation so that said generally hemispherical articulating surface defines a truncated ball; and a stem attached to the head, which arises from the truncation of the head and includes at least one of the following features:
>
> A) a general angle of attachment to the head which is acute in relation to the truncation of the head;
>
> B) a flanged cross-sectional stem profile;
>
> C) an inwardly curved stem;
>
> D) an eccentric head attachment site for the stem;
>
> wherein said implant has its head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and its stem of a size for intramedullary insertion in metacarpal bone stock.

The Rejection Under Section 102

Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or recognition of inherent properties that may be possessed by the reference. See Verdegaal Brothers Inc. v. Union Oil Co. of California, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). Nor does it require that the reference teach what the applicant is claiming, but only that the claim on appeal "read on" something disclosed in the reference, *i.e.*, all limitations of the claim are found in the reference. See Kalman v. Kimberly-Clark Corp, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984).

Claims 1 and 3 stand rejected as being anticipated by Whipple. It is the examiner's view that Whipple discloses in Figure 3B a thumb joint prosthesis having a flanged stem profile and a head of generally hemispherical shape that is uninterrupted up to its truncation (Paper No. 25, page 3). The appellant argues in opposition that Whipple does not anticipate the subject matter of these claims because (1) it does not disclose a flanged cross-sectional profile, (2) the head is made to mate with a second

manufactured component rather than bone, and (3) the head is not generally hemispherical in shape (Brief, pages 4 and 5; Reply Brief, pages 3 and 4). We are not persuaded by any of these arguments that the rejection should not stand, and therefore we shall sustain it. Our reasoning follows.

Claim 1 requires that the stem have a flanged cross-sectional profile. The common applicable definition of "flange" is a "rib or rim for strength, for guiding, or for attachment to another object,"[1] As the examiner has pointed out, the projections and notches shown in Figure 3B of Whipple constitute "flanges" when the stem is viewed in an appropriate cross-section. Additionally, although unnumbered, a flange clearly is present in Whipple's Figure 3B at the base of the stem, spaced slightly from the truncation of the head, and a cross-section taken through this portion of the stem would be "flanged." Thus, this feature of claim 1 is disclosed by Whipple.

The fact that the Whipple thumb joint implant element shown in Figure 3B is described in conjunction with mounting in a corresponding second implant element rather than directly into bone does not disqualify it as an anticipatory element. As we pointed about above in relating the guidance provided by our reviewing court for evaluating rejections under Section 102, anticipation requires only that the claim read on something disclosed in the reference, and such is the case here.

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[1]See, for example, Webster's New Collegiate Dictionary, 1973, page 436.

As pictured in the appellant's drawings, the head of the implant is in the shape of a hemisphere, that is, one-half of a sphere. As recited in claim 1, however, and as explained in the specification, the invention comprises a head having "a single, smooth, generally hemispherical" articulating surface with "a generally abrupt, distally directed truncation thereto." The presence of the amplifying term "generally"[2] causes claim 1 not to be limited only to an exact hemispherical shape. The question then becomes what constitutes a "generally" hemispherical surface as opposed to a surface that is not "generally" hemispherical, and this question is not precisely answered in the specification. It is, however, clear from the language used in claim 1 that a complete hemisphere is not required, a conclusion that is confirmed by the further recitation in the claim that the "generally hemispherical" surface terminates in "a generally abrupt . . . truncation thereto." To "truncate" is to shorten by or as if cutting off,[3] and thus a truncation of a hemisphere is less than a hemisphere.

We therefore agree with the examiner that in Figure 3B Whipple discloses an implant head that is "generally hemispherical . . . continuous . . . and uninterrupted up to said truncation," as is stated in claim 1. This understanding is further supported by Whipple's own description of the metacarpal component (122) as being of "a generally

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[2]The common definition for "generally" is "in disregard of specific instances with regard to an overall picture." Webster's New Collegiate Dictionary, 1973, page 478.

[3]Webster's New Collegiate Dictionary, 1973, page 1255.

truncated hemispherical shape" (col 2, lines 17-29). Since Whipple thus discloses all of the subject matter recited in claim 1, the claim is anticipated, and we will sustain the Section 102 rejection thereof. The like rejection of claim 3 is sustained inasmuch as the appellant has elected to group in with claim 1 (Brief, page 3).

The Rejections Under Section 103

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

Claims 1-7, 21, 22, 24 and 25 stand rejected as being unpatentable over Klawitter, which is directed to a joint replacement for a human finger. With reference particularly to Figures 3A and 5, the examiner is of the view that all of the subject matter recited in claim 1 is disclosed by Klawitter, except that the head has cuts (52) removed

to allow passage of the ligaments and therefore does not teach a head surface that is "continuous as to its sphericity and uninterrupted up to said truncation," as is required by independent claims 1, 21 and 24. However, it is the examiner's position (Paper No. 25, page 4) that

> [i]t would have been obvious to one of ordinary skill in the art not to remove material from the joint head that forms a relief cut in the metacarpel element of Klawitter in order to use for a joint that does not obstruct the path of the ligaments. The manufacturing of an "uninterrupted" head is a step backward in the art.

We do not agree.

Even if Klawitter is considered, arguendo, to be analogous art (the appellant argues that it is not because it is directed to finger joints), we fail to perceive any teaching, suggestion or incentive which would have led one of ordinary skill in the art to manufacture the Klawitter joint implant without the cuts necessary to allow passage of the ligaments of the finger, for to do so would render the device unsuitable for its intended purpose. Continuing on the same theme, there is no evidence from which to conclude that one of ordinary skill in the art would have found it obvious to utilize the Klawitter joint implant on the thumb, in view of the different considerations necessary for a thumb joint, which are attested to on page 10 of the Pringle declaration.

It therefore is our conclusion that Klawitter does not establish a prima facie case of obviousness with regard to the subject matter recited in independent claims 1, 21

and 24 or, it follows, of dependent claims 2-7, 22 and 25, and we will not sustain this rejection.

Claims 21 and 22 are rejected as being unpatentable over Whipple. The appellant has urged at the outset that Whipple constitutes nonanalogous art in that it is directed to a two-piece joint implant rather than the one-piece implant to which claims 21 and 22 are directed. We find this argument not to be persuasive. It is our opinion that Whipple would have commended itself to an inventor's attention in considering the problems of thumb joints because it also deals with the replacement of joints in the hand. See In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992). While the appellant has argued that this would not be the case, no evidence has been presented in support thereof, and argument and conclusionary statements of the applicant do not constitute objective evidence of nonobviousness. See In re deBlauwe, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984). Also in this regard, it is interesting to note that claim 21 does not contain the "wherein" clause of the last four lines of claim 1, which states that the head is sized for mounting in a concavely prepared surface of trapezium bone stock, and this would seem to undermine the appellant's assertion in the nonanalogous art argument that the claim is directed to a device to be implanted only in bone.

We have discussed Whipple above in the context of the Section 102 rejection of claim 1. Claim 21 differs from claim 1 in that it further requires the head to have a diameter of 13mm to 19mm. However, while Whipple is silent as to the dimensions of the thumb implant disclosed therein, it is our view that it would have been obvious to one of ordinary skill in the art to provide a thumb joint implant with appropriate dimensions for implantation in a particular human being, such as the claimed range, for in an obviousness assessment skill is presumed on the part of the artisan, rather than the lack thereof. In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

We therefore conclude that Whipple establishes a prima facie case of obviousness with regard to the subject matter recited in claim 21, and we will sustain the rejection of claim 21 and of claim 22, the separate patentability of which was not argued.

CONCLUSION

The rejection of claims 1 and 3 as being anticipated by Whipple is sustained.

The rejection of claims 1-7, 21, 22, 24 and 25 as being unpatentable over Klawitter is not sustained.

The rejection of claims 21 and 22 as being unpatentable over Whipple is sustained.

A rejection of claims 1, 3, 21 and 22 having been sustained, the decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

NEAL E. ABRAMS
Administrative Patent Judge)
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CHARLES E. FRANKFORT) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES
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JOHN P. McQUADE)
Administrative Patent Judge)

NEA:pgg

CHRISTOPHER JOHN RUDY
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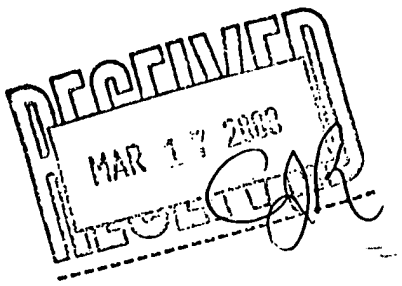
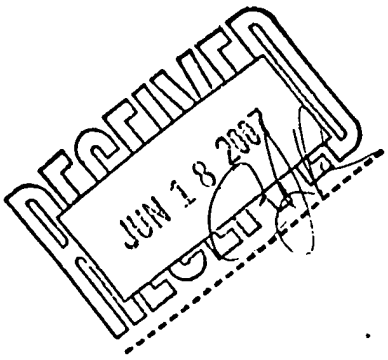


The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHARLES O. TOWNLEY



Appeal 2007-0570
Application 09/352,472
Technology Center 3700

Decided: June 14, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 31-54, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a basal thumb joint implant. Claim 31 is illustrative:

31. A basal thumb joint implant comprising a head including a single, smooth, generally hemispherical, medio-proximally directed, articulating surface, and a generally abrupt, distally directed, planar end to the head, which defines an end to said articulating surface, said articulating surface being continuous as to its sphericity and uninterrupted up to the end of said articulating surface so that said articulating surface defines a truncated ball of a shape that is from substantially hemispherical to greater than substantially hemispherical; and a stem attached to and projecting from the head along an axis, which arises from the generally planar end to the head and includes at least one of the following features:

(A) a general angle of projection from the head, which is acute in relation to the generally planar end to the head so as to help align the stem in intramedullary bone stock that has been resected substantially normal to its proximal end;

(B) a flanged cross-sectional stem profile, which , when taken in cross-section perpendicularly to the stem, is in a tri-flange shape, with three flanges without notches extending distally on the stem, which helps provide for a precise fit with metacarpal medullary canal anatomy, hence preserving bone stock and assuring optimal long term stability, including near if not complete immovability with respect to rotation, of the implant;

(C) an inwardly curved stem so as to help avoid a propensity for dislocation of a replaced joint, and which helps provide for a precise

fit with metacarpal medullary canal anatomy, hence preserving bone stock and assuring optimal long term stability, including near if not complete immovability with respect to rotation, of the implant; and

(D) an eccentric head attachment site for the stem so as to help avoid a propensity for dislocation of a replaced joint;

wherein said implant has its head of a size for mounting in and articulating with a correspondingly concavely prepared surface of trapezium bone stock; its stem of a size for intramedullary insertion in metacarpal bone stock; and such feature(s) of an anatomically oriented arrangement help(s) permit an unobstructed range of normal pain free motion.

The Examiner relies on the following prior art references to show unpatentability:

Smith	US 3,314,420	Apr. 18, 1967
Bekki	US 5,007,932	Apr. 16, 1991

Wright Technology brochure of the Swanson implant submitted on 9/1/99.

The rejections as presented by the Examiner are as follows:

1. Claims 31-40, 42-44, 47, 48, 50-52, and 54 stand rejected under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention.

2. Claims 45, 46, 49, and 53 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki.

3. Claims 31, 36, and 41 stand rejected under 35 U.S.C § 103(a) as unpatentable over Wright and Smith.

We reverse.

DISCUSSION

Public Use and Sale:

Claims 31-40, 42-44, 47, 48, 50-52, and 54 stand rejected under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention. In addition, claims 45, 46, 49, and 53 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki. The Examiner relies on Smith and Bekki to teach prosthetic devices made from a ceramic material (Answer 4-5). According to the Examiner, the use of ceramic materials provides joint implant devices with a lighter weight and better bone ingrowth properties. However, neither Smith nor Bekki teach the structural requirements of Appellant's claimed implant.

To reach the structural requirements of Appellant's claimed implant, the Examiner relies on Appellant's admission that the implant was sold more than one year prior to the filing date of the application (Answer 3). Appellant does not dispute that the claimed implant was sold prior to the filing date of the instant invention. To the contrary, Appellant specifically discloses that the device was sold and used more than one year prior to the filing date (Information Disclosure Statement (IDS)[1] 2-3). Appellant asserts, however, that the sale and use of the device prior to the filing date of the application falls within the scope of the experimental use exception (Br. 4-12).

Therefore, we find that the decisive issue before us is whether the sale and use of Appellant's claimed implant more than one year prior to the filing

[1] Received September 1, 1999.

date of the application falls within the experimental use exception. In our opinion, the weight of the evidence falls in favor of Appellant.

> [T]he question posed by the experimental use doctrine, assessed under the first prong of the two-part on-sale bar test of *Pfaff* [*v. Wells Elecs.*, 525 U.S. 55, 67-68, 48 USPQ 1646, 1647 (1998)], is not whether the invention was under development, subject to testing, or otherwise still in its experimental stage at the time of the asserted sale. Instead, the question is whether the transaction constituting the sale was not incidental to the primary purpose of experimentation, *i.e.*, whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation.

Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1210, 75 USPQ2d 1650, 1654 (Fed. Cir. 2005). Accordingly, it is necessary to look "to objective evidence to show that a pre-critical date sale was primarily for experimentation." *Id.* at 1212, 75 USPQ2d at 1656. Our appellate reviewing court has catalogued and consolidated a list of factors that are representative of the "various kinds of evidence relevant to the question of whether pre-critical date activities involving the patented invention-either public use or sale were primarily experimental and not commercial." *Id.* at 1213, 75 USPQ2d at 1657, citing *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353, 63 USPQ2d 1769, 1779 (Fed. Cir. 2002). Appellant has specifically addressed these factors and supported his assertions with the Declarations of Leslie, Townley, and Pringle[2] (Br. 5-12).

[2] Executed February 9, 2004, the second Pringle declaration.

In sum, the evidence of record establishes, *inter alia*, that:

1. The basal thumb joint implant was offered to Mark S. Leslie, M.D., an orthopedic hand surgeon, as a first user, prior to the critical date. "Dr. Leslie was informed as a condition of his use that the basal thumb joint implant was experimental, and he acknowledged this prior to conveyance of the implant" (Townley Declaration 4). Dr. Leslie also understood that the device was to be tried in confidence (Leslie Declaration 3).

2. The inventor retained control over the experimental use of the device (Leslie Declaration 2 ("performance of the implant was to be closely monitored and reported to BioPro. Inc."); Townley Declaration 4 ("Dr Leslie "was informed and he understood that he was to closely monitor and keep track of results")).

3. Despite the experimental use of the implant, it was customary in this industry to sell the device in order to recoup some of the development costs of the implant (Br. 8; Townley Declaration 4).

4. The doctor using the implant, Dr. Leslie, considered his use of the implant experimental because it was "clearly different from the otherwise broadly analogous Swanson Titanium basal thumb joint known than, and thus, . . . their configuration should require a clinical trial to determine if the new basal thumb joint implants could be adequately employed in general" (Leslie Declaration 3. *See also* Pringle Declaration 4 ("it would be appropriate to desire to field test a device that has passed a simple FDA record review for a certain level of safety and effectiveness to see if its improvements engender a higher level of effectiveness in vivo than required by FDA and to see if further modifications would be in order. That is what was done with . . . Dr. Leslie. . .")).

5. "[T]he length of the test period was only that necessary to evaluate the device under field conditions. It was only about a year overall, with the sole pre-critical date sale occurring in the first two months of that. The present application was filed promptly after a satisfactory technical evaluation period ended" (Br. 8; IDS 3; Townley Declaration 5 ("Based upon the reports from Dr. Leslie, and my own work, I became satisfied that the implant was successfully performing technically in the filed, and . . . the present application was diligently prepared and filed.")).

6. There was no commercial exploitation of the device prior to the critical period (Townley Declaration 4).

In our opinion, this evidence strongly suggests that the sale and use of the claimed device prior to the critical date was for experimental purposes, and therefore the sale and use of the claimed device prior to the critical date falls within the experimental use exception.

For his part, the Examiner finds that experimental use has not been established because Appellant received payment for the device, which was FDA approved. In addition, the Examiner finds that Appellant failed to favor this record with documented evidence of a confidentiality agreement, any modification to the device as a result of the experimental use, or the records maintained during the experimental use. The Examiner does not, however, make any attempt to address the declaratory evidence or weigh this evidence in the context of the factors set forth in *Allen Eng'g Corp.* At best, the Examiner has simply stated his unsupported opinion that the evidence of record is insufficient to establish that the use of the device prior to the critical date was for experimental purposes. Accordingly, when viewed as a whole, we find that the weight of the evidence falls in favor of Appellant.

The sale and use of the device prior to the critical date was for experimental purposes and falls within the experimental use exception.

Accordingly, we reverse the rejection of claims 31-40, 42-44, 47, 48, 50-52, and 54 under 35 U.S.C. § 102(b) based upon an admitted public use or sale of the invention.

Having found that the use and sale of the device prior to the critical date falls within the experimental use exception, the combination of Appellant's admitted public use and sale of the invention with Smith or Bekki must also fall because neither secondary reference teaches Appellant's claimed implant. Accordingly, we reverse the rejection of claims 45, 46, 49, and 53 under 35 U.S.C. § 103(a) as unpatentable over the public use of the invention in view of Smith or Bekki.

Wright and Smith:

Claims 31, 36, and 41 stand rejected under 35 U.S.C § 103(a) as unpatentable over Wright and Smith. Claim 31 is drawn to a basal thumb joint implant. The implant includes, *inter alia*, at least one of the following features: (A) an acute projection angle, (B) a flanged cross-sectional stem profile, (C) an inwardly curved stem, and (D) an eccentric head attachment. Claim 36 depends from and further limits claim 31 to require that the implant has at least the eccentric head attachment site for the stem.

The Examiner finds that Wright teaches a basal thumb joint implant having a head that is "'eccentrically attached to the stem' since it appears

off-centered and is not a complete ball head" (Answer 4). In contrast, Appellant asserts that

> [t]he head of the Wright . . . implant does not appear to be eccentrically attached to the stem. It is not off-centered. See, the reproduced photo on the first (cover) page of the Wright brochure; the drawing on the bottom portion of the brochure's third page; and the X-ray on the top right hand side of the brochure's fourth page.

(Reply Br. 1.) In response, the Examiner does nothing more than reassert that Wright teaches an eccentric attachment site (Answer 6). Upon review of Wright, we find that the weight of the evidence falls in favor of Appellant. Wright's photo, schematic and X-rays (Wright cover page and 2-5) fail to illustrate an implant which has an eccentric head attachment site for the stem so as to help avoid a propensity for dislocation of a replaced joint as required by claims 31 and 36. In addition, the Examiner fails to direct our attention to any portion of Wright, and we find none, to suggest that the implant has an eccentric head attachment site for the stem. Accordingly, we find that Wright fails to support the Examiner's prima facie case of obviousness.

Claim 41 depends from and further limits claim 31 to require that the implant is made of a suitable ceramic material. Recognizing that Wright does not teach the use of a ceramic for the implant, the Examiner relies on Smith to teach a prosthesis formed from a ceramic material (Answer 4). Smith does not, however, make up for Wright's failure to teach an eccentric head attachment site for the stem.

For the foregoing reasons, we reverse the rejection of claims 31, 36, and 41 under 35 U.S.C § 103(a) as unpatentable over Wright and Smith.

CONCLUSION

In summary, we reverse all rejections of record.

REVERSED

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